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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,813	01/10/2007	William Nadler	294271US0PCT	2168
22850 7590 06/16/2009 OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314				
EXAMINER LOEWI, SUN JAE Y				
ART UNIT 1626		PAPER NUMBER		
NOTIFICATION DATE 06/16/2009		DELIVERY MODE ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com  
oblonpat@oblon.com  
jgardner@oblon.com

### Office Action Summary

**Application No.**

10/590,813

**Applicant(s)**

NADLER ET AL.

**Examiner**

SUN JAE Y. LOEWE

**Art Unit**

1626

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 10 and 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-85/86)  
Paper No(s)/Mail Date 9-19-2006/8-25-2006
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. Claims 1-12 are pending in the instant application. The miscellaneous office communication dated February 24, 2009 is withdrawn in view of the interview dated March 12, 2009.

#### *Election/Restrictions*

2. Applicant's election with traverse of the species of Example 1 (see below) in the reply filed on February 24, 2009 is acknowledged.

**Example 1:** ~~Preparation of (2S,4S and 4Z)-N-(2S)-2-hydroxy-2-phenyl-ethyl-4-(methoxyimino)-1-f(2'-methoxy(1,1'-biphenyl)-4-yl)carbamoyl-2-pyrrolidone carboxamide~~

The traversal is on the ground(s) that the search of the full scope of the claims would not impose a serious burden. This argument has been considered, however, it is not found to be persuasive. The instant application is a national stage entry of PCT/EP05/50852, therefore the criteria of burden does not apply.

3. Pursuant MPEP 1893.03

“(Excerpts)

Once the national stage application has been taken up by the examiner, prosecution proceeds in the same manner as for a domestic application with the exceptions that:

(A) the international filing date >>(or, if appropriate, the priority date)< is the date to keep in mind when searching the prior art; and

(B) unity of invention proceeds as under 37 CFR 1.475.

.....

¶ 18.20 National Stage Election of Species in 35 U.S.C.

*371 Applications*

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

[1]

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a). ”

the search and examination detailed in this office action was performed following the guidelines provided by MPEP 803.02

*“(Excerpts)*

Markush-type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. If the Markush-type claim is not allowable \*\*, the provisional election will be given effect and examination will be limited to the Markush-type claim and claims to the elected species, with claims drawn to species patentably distinct from the elected species held withdrawn from further consideration.

If on examination the elected species is found to be anticipated or rendered obvious by prior art, the Markush-type claim and claims to the elected species shall be rejected, and claims to the nonelected species would be held withdrawn from further consideration.”

The elected was not allowable. Therefore, the provisional election of species was given effect and non-elected species were withdrawn from further consideration. Applicant will be entitled to rejoinder and consideration of non-elected species upon allowability of the generic claims.

4. Claims 10 and 11 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected subject matter. Applicant timely traversed the restriction (election) requirement in the reply filed on March 3, 2008.

***Priority***

5. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

***Information Disclosure Statement***

6. The information disclosure statements (August 25, 2006 and September 19, 2006) were in compliance with the provisions of 37 CFR 1.97 and 37 CFR 1.98. The statements were considered. Signed copies of form 1449 are enclosed herewith.

***Claim Objections***

7. Claim 12 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claim 12 depends of claim 11 which does not encompass the elected species. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject

matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-9 and 12 rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/72705 in view of WO 2004/076407.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Scope and Contents of the Prior Art

WO 01/72705 teaches the preparation of  
(2S,4EZ)-N-(2-hydroxyethyl)-4-(methoxyimino)-1-({2'-methyl[1,1'-biphenyl]-4-yl}carbonyl)-  
2-pyrrolidinecarboxamide  
according to a procedure encompassing the steps below:

(2S)-1-(*tert*-butoxycarbonyl)-4-oxo-2-pyrrolidinecarboxylic acid  $\longrightarrow$   
(2S,4EZ)-1-(*tert*-butoxycarbonyl)-4-(methoxyimino)-2-pyrrolidine-carboxylic acid -pg. 50 of reference  
(equivalent to instant step 3)

(2S,4EZ)-1-(*tert*-butoxycarbonyl)-4-(methoxyimino)-2-pyrrolidine-carboxylic acid  $\longrightarrow$  amide  
- pg. 64 of reference ( equivalent to instant step 4)

WO 2004/076407 teaches the following processes:

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- pg. 20 of reference

(equivalent to instant step 1)



- pg. 19 of reference (equivalent to

instant step 2)

Ascertaining the Differences between the Prior Art and Claims at Issue

The instant process is taught by the combination of the steps disclosed in the prior art.

Resolving the Level of Ordinary Skill – Prima Facie Case of Obviousness

The references provide process of making compounds which encompass the instantly  
 (2*S*,4*EZ*)-*N*-(2-hydroxyethyl)-4-(methoxyimino)-1-[(2'-methyl[1,1'-biphenyl]-4-yl)carboxyl]-  
 elected 2-pyrrolidinecarboxamide

The reference of WO 01/72705 teaches the preparation of the above named species, which is a BAX inhibitor. The motivation to combine the prior art teachings is to practice alternate processes to obtain a final product that has pharmacological utility. Thus, the rationale that the instant claims are obvious is that "a person of ordinary skill has good reason to pursue the known options within his or her technical grasp." See MPEP 2143.E.

The instant claims are *prima facie* obvious over the prior art references.

**Conclusion**

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUN JAE Y. LOEWE whose telephone number is (571)272-9074. The examiner can normally be reached on M-F 7:30-5:00 Est.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sun Jae Y. Loewe/  
6-10-2009